

320-N HEPATITIS C (HCV) PRIOR AUTHORIZATION REQUIREMENTS FOR DIRECT ACTING ANTIVIRAL MEDICATION TREATMENT FOR AHCCCS MEMBERS AGE 18 YEARS AND OLDER

REVISION DATE: 10/01/16, 03/15/15, 08/01/14

INITIAL
EFFECTIVE DATE: 07/17/2014

Description

This Policy delineates AHCCCS prior authorization requirements for Title XIX and XXI members eighteen years and older for coverage of direct acting antiviral medications for treatment of Hepatitis C virus (HCV). These medications include, but are not limited to, Epclusa, Harvoni, Zepatier, Technivie, Viekira, and their successors. All such medications require prior authorization from AHCCCS for FFS members or its Contractors, as applicable.

Amount, Duration and Scope

In order to obtain prior authorization approval of HCV direct acting antiviral medications, members must meet all of the following requirements:

1. Are age ≥ 18 years; and
2. Have a diagnosis of HCV which has been confirmed by detectable serum HCV RNA by quantitative assay completed within the past 90 days from the date of the prior authorization request; and
3. Are prescribed HCV medications by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician; and
4. Have a diagnosis of liver fibrosis/cirrhosis as further described in 4a-4b and meet all other requirements specified for the applicable Metavir score. The Metavir score must be established through testing which is completed no earlier than 90 days from the date of the prior authorization request. Contractors may require additional testing to confirm the values identified below.
 - a. *Fibrosis F2 score or greater.* The diagnosis of liver fibrosis/cirrhosis of Metavir stage F2 or greater must be evidenced by biopsy, Fibroscan, elastography, Fibrosure/FibroTest-Actitest level, or APRI as described in Table 1; or



- b. Members who have one of the conditions in (i)-(v) below, regardless of fibrosis level:
- i. Member is recently post liver transplantation, or
 - ii. Member is diagnosed with Stage I-III Hepatocellular Carcinoma meeting Milan Criteria, or
 - iii. Member is diagnosed with Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations, or
 - iv. Member is diagnosed with HCV induced renal disease (e.g. nephrotic syndrome, membranoproliferative glomerulonephritis (MPGN), or
 - v. Member is diagnosed with leukocytoclastic vasculitis.

Table 1

Metavir Score	Biopsy	Fibroscan	Elastrography (ARFI/PSWE)	Fibrosure / Fibrosure-Actitest	APRI
F4	F4	> 12.5 kPa	> 2.34 m/s	> 0.75	> 2.0
F3	F3	9.6 – 12.4 kPa	2.01 – 2.33 m/s	0.58 – 0.74	1.5 – 1.9
F2	F2	7.1 – 9.5 kPa	1.38 – 2.0 m/s	0.49 – 0.57	1.0 – 1.4
F1/0	F1/0	< 7.0 kPa	< 1.37 m/s	< 0.48	< 0.9

As a prerequisite to requesting direct acting antiviral medications for treatment of Hepatitis C, members must have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity.

If a member has a substance use disorder in the past 12 months from the request date for treatment, the member must be in remission for the past three months from the request date for treatment and must be engaged in a substance use disorder treatment program at the time of the prior authorization request and over the course of treatment if the HCV medications are approved.

A. TREATMENT MONITORING REQUIREMENTS

1. Members prescribed HCV treatment must participate in a treatment adherence program.
2. At a minimum, providers are responsible for completing HCV viral load laboratory testing at weeks 4, 12, and 24 for members approved for 12 week HCV regimens.
3. At a minimum, providers are responsible for completing HCV viral load laboratory testing at weeks 4, 12, 24 and 48 for members approved for 24 week HCV regimens.



4. Providers are required to monitor hemoglobin levels periodically when a member is prescribed ribavirin.

B. LIMITATIONS

HCV coverage is not provided for the following:

1. Monotherapy of:
 - a. Daclatasvir (Daklinza)
 - b. Simeprevir (Olysio)
 - c. Sofosbuvir (Sovaldi)
2. Sofosbuvir for greater than 24 weeks of therapy.
3. Direct Acting Antiviral Dosages greater than the FDA approved maximum dosage.
4. Ombitasvir, Paritaprevir and Ritonavir (Technivie) or Ombitasvir, Paritaprevir and Ritonavir; Dasabuvir tablets (Viekira Pak) shall not be approved for members whose Child Pugh score is B or C.
5. Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request.
6. Members when there is documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures.
7. Members declining to participate in a treatment adherence program.
8. Members with decompensated liver disease (i.e., Child-Pugh score >9).
9. Members whose comorbidities are such that their life expectancy is one (1) year or less.
10. Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.)
11. Greater than one course of therapy per lifetime.
12. Lost or stolen medication absent of good cause.
13. Fraudulent use of HCV medications.



C. REQUIRED DOCUMENTATION FOR SUBMISSION OF HCV PRIOR AUTHORIZATION REQUESTS

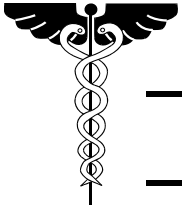
In order for a prior authorization request for HCV medications to be considered, the following minimum information must be submitted for the member:

- Evidence of liver fibrosis as referenced in I.4a-4b.
- HCV treatment history and responses.
- Evidence of Hepatitis A & B vaccinations or laboratory evidence of immunity.
- Current medication list.
- Laboratory results for all of the following:

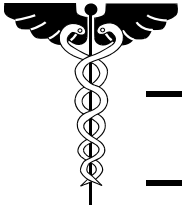
HCV screen, genotype and current baseline viral load, total bilirubin, albumin, INR, CrCl or GFR, LFTs, CBC and drug/alcohol screen completed within the past 90 days.

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